

October 12, 2001

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT
REPORT NO. OAR-01-08, "OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY
ASSURANCE, AUDIT NO. BSC-ARP-01-04, OF THE BECHTEL SAIC
COMPANY, LLC"

Dear Mr. Milner:

Enclosed is the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-01-08) of the U.S. Department of Energy's (DOE's) audit of BSC. This audit was conducted August 20 through 24, 2001, at BSC's facility at Las Vegas, Nevada.

The audit team performed a limited-scope performance-based quality assurance (QA) audit, to evaluate BSC's implementation of the applicable provisions of the OCRWM Quality Requirements and Description (QARD) document, DOE/RW-0333P, Revision 10, and associated implementing procedures. During the audit, the audit team assessed the adequacy and effectiveness of the QARD procedures and verified compliance with requirements in the areas reviewed.

The DOE audit team evaluated BSC's processes and activities that support the Total System Performance Assessment for the Site Recommendation (TSPA-SR) technical report. The team evaluated the quality of the report by examining the development/analyses of scenarios; traceability/transparency of assumptions, uncertainties, and alternative conceptual models; data and other input; and software control. The audit team also assessed the defensibility of the TSPA-SR results/conclusions and evaluated the overall effectiveness of the TSPA-SR technical report.

The NRC observers (hereafter, observers) determined that DOE's audit of BSC was effective in identifying potential deficiencies and recommending improvements for the documentation and QA procedures reviewed. During the conduct of the audit, both the audit team and the observers independently reviewed applicable QA procedures, analysis reports, models, and software documentation. The observers did not submit any audit observer inquiries requesting clarification and information on audited documents.

The DOE audit team identified one potential deficiency in the area of software and one potential significant deficiency in the area of traceability/transparency. The potential significant deficiency was identified as a repetitive condition, based on similar deficiencies identified during previous audits. The staff reviewed the DOE audit team findings and agreed with the results as presented at the post-audit briefing to the DOE management. The staff believes that this DOE audit was well-planned, thorough, and adequately evaluated BSC's activities supporting TSPA-SR.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. Although the audit team identified potential deficiencies, the

observers believe that BSC's implementation of its quality program, in the areas reviewed during the audit, was generally acceptable.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter at (301) 415-6684.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-01-06, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality
Assurance, Audit No. BSC-ARC-01-10,
of the Bechtel SAIC Company, LLC"

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. Although the audit team identified potential deficiencies, the observers believe that BSC's implementation of its quality program, in the areas reviewed during the audit, was generally acceptable.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter at (301) 415-6684.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-01-06, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality
Assurance, Audit No. BSC-ARC-01-10,
of the Bechtel SAIC Company, LLC"

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Letter to R.A. Milner from C.W. Reamer dated ____ October 12, 2001 ____

cc:

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| I. Zabarte, W.S.N.C. | |

U.S. NUCLEAR REGULATORY COMMISSION
INPUT FOR THE OBSERVATION AUDIT REPORT NO. OAR-01-08,
“OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT NO. BSC-ARP-01-04
BECHTEL SAIC COMPANY, LLC”

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Enclosure

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission's (NRC's) Division of Waste Management observed the U.S. Department of Energy's (DOE's), OQA, audit of BSC. BSC is DOE's Management and Operating contractor. OQA conducted this audit on August 20 through 24, 2001.

The audit team performed a limited-scope performance-based quality assurance (QA) audit to evaluate BSC's implementation of the applicable provisions of the OCRWM Quality Requirements and Description (QARD) document, DOE/RW-0333P, Revision 10, and BSC's compliance with associated implementing procedures in the following areas:

The DOE audit team evaluated BSC's processes and activities that support the Total System Performance Assessment for the Site Recommendation (TSPA-SR) technical report. The team evaluated the quality of the report by examining the development/analyses of scenarios; traceability/transparency of assumptions, uncertainties, and alternative conceptual models; data and other input; and software control. The audit team also assessed the defensibility of the TSPA-SR results/conclusions and evaluated the overall effectiveness of the TSPA-SR technical report.

The objectives of the audit were to assess the adequacy and effectiveness of the QARD procedures and to verify BSC's compliance with requirements in the areas reviewed. The objective of the NRC observation was to assess whether BSC had properly implemented the provisions contained in the QARD and the requirements contained in Subpart G, "Quality Assurance," to Part 60 of Title 10 of the U.S. Code of Federal Regulations (10CFR).

This report addresses the NRC observers' (hereafter, observers') determination of the effectiveness of the OQA audit, and whether BSC implemented adequate QARD controls.

2.0 MANAGEMENT SUMMARY

The observers determined that OQA Audit BSC-ARP-01-04 was effective in determining the level of compliance of evaluated BSC QA activities with the QARD and associated implementing procedures. During the conduct of the audit, both the audit team and the observers independently reviewed applicable QA procedures, analysis reports, models, and software documentation. The observers found that the audit team members were qualified, independent of the activities that they reviewed, and knowledgeable of the QA requirements and the technical disciplines in the areas in which they performed assessments. The audit team identified two conditions adverse to quality that were documented as potential deficiencies. The observers agreed with the audit team's conclusion that the OCRWM QA program had been satisfactorily implemented, except for the identified potential deficiencies. The observers did not submit any audit observer inquiries requesting clarification and information on audited documents.

3.0 AUDIT PARTICIPANTS

3.1 Observers

| | | |
|---------------------|----------|--|
| Ted Carter | Observer | NRC |
| Robert K. Johnson | Observer | NRC |
| David Esh | Observer | NRC |
| Thomas C. Trbovich | Observer | Center for Nuclear Waste Regulatory Analyses (CNWRA) |
| Patrick A. LaPlante | Observer | CNWRA |
| Michael A. Smith | Observer | CNWRA |

3.2 Audit Team

| | | |
|-----------------|----------------------|------------------------------------|
| Marilyn Kavchak | Audit Team Leader | OQA/Navarro Quality Services (NQS) |
| Harvey Dove | QA Auditor | OQA/NQS |
| Donald Harris | QA Auditor | OQA/NQS |
| Sam Archuleta | Technical Specialist | OQA/NQS |
| Mark Nutt | Technical Specialist | OQA/NQS |
| Frank Wong | Technical Specialist | OQA/NQS |
| Alf Wikjord | Technical Specialist | OQA/NQS |

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

OQA conducted this audit of BSC in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." NRC observed this audit based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The audit team conducted a limited-scope performance-based audit of activities and processes related to BSC's implementation of the QARD. The DOE audit team evaluated BSC's processes and activities that support the Total System Performance Assessment for the Site Recommendation (TSPA-SR) technical report. The team evaluated the quality of the report by examining the development/analyses of scenarios; traceability/transparency of assumptions, uncertainties, and alternative conceptual models; data and other input; and software control. The audit team also assessed the defensibility of the TSPA-SR results/conclusions and evaluated the overall effectiveness of the TSPA-SR technical report.

4.2 Conduct and Timing of the Audit

The observers determined that the audit was performed effectively and that the audit team demonstrated an understanding of the applicable DOE and BSC programs and procedures. The observers also determined that the audit team members conducted thorough interviews; that they challenged responses, when appropriate; and that they effectively used their detailed audit checklist. The observers concluded that the timing of the audit was appropriate for the audit team to evaluate ongoing BSC activities. The audit team and the observers caucused at the end of each day. The audit team held daily meetings with BSC management (with the observers present) to discuss the current audit status and the preliminary audit findings.

4.3 Audit Team Qualification and Independence

The observers reviewed the qualifications of the audit team members for accuracy and completeness in accordance with the requirements of Procedure QAP 18.1, "Auditor Qualification." The observers also examined the levels of training, education, and experience of the audit team members. The observers concluded that the audit team members had the necessary expertise and were well-prepared to audit the subject matter in the QA program.

4.4 Examination of the QA Elements

The OQA programmatic and technical activities were conducted simultaneously, using a team consisting of one technical specialist and one programmatic QA auditor. Often, during the audit, certain programmatic aspects of the documents audited were independently reviewed by an audit team member. The observers determined that the limited-scope audit focused on the QA elements closely associated with the significant process steps of technical report development. The team evaluated the quality of the TSPA-SR report by examining the development and analysis of scenarios; performance of calculations and sensitivity analysis; incorporation of design changes; traceability/transparency of assumptions, uncertainties of and alternative conceptual models; data and other input; and software control, while assuring compliance with the QARD requirements, as implemented in the BSC quality procedures. In addition, a review of the status of OCRWM deficiency documents LVMO-00-117 through 121 was also performed.

4.4.1 AP-2.21Q, Rev. 0, ICN 0, "Quality Determinations and Planning activities for Scientific, Engineering, and Regulatory Compliance Activities"

The Technical Work Plan (TWP) for Total System Performance Assessment, TWP-MGR-PA-000001, Rev 01, dated 2-27-01, was reviewed and found to be in compliance with the procedural requirements. The OCRWM Activity Evaluation form had been properly executed.

The observers agreed with the audit team's findings in this area.

4.4.2 AP-2.14Q, Rev. 1, ICN 0, "Review of Technical Products and Data"

The auditors examined the check and back check record copies of the report/ICN revisions and determined the checking activities had been accomplished in accordance with procedural requirements. Comment/resolution forms had been completed and check personnel had proper qualification and training. The review of these records was difficult because of the disorganization of the individual record packages. Because of the late arrival of these records from archival storage, the QA auditor will continue this review the week following the audit.

4.4.3 AP-SI.1Q, Rev. 3, ICN 0, "Software Management"

Two potential deficiencies were identified in this area. The software program, ASHPLUME, had version 1.4LV and 2.0 identified in the report as being used. Version 1.4LV had been properly qualified and validated. Since Version 2.0 had not undergone qualification and validation, this was identified as the first deficiency. In addition, since the code had not been documented and identified as unqualified "for interim use," as described by the procedure, a second deficiency was noted.

The observers agreed with the audit team's findings in this area.

4.4.4 AP-3.11Q, Rev. 1, ICN 3, “Technical Reports” AP-3.12Q, Rev. 0, ICN 3, “Calculations”

The review of the report Appendix G calculations revealed a potential discrepancy. It appears the calculation review was not performed to the more stringent requirements of AP-3.12Q but rather to the less restrictive requirements of AP-3.11Q. Discussions indicated disagreement over the interpretation and applicability of the requirements of each procedure. The observers agreed with this deficiency.

Further review of the data packages and models in this area led to the determination of repetitive conditions that had been previously identified in LVMN-01-D-118 and LVMO-99-C-001, dealing with transparency issues. The audit team determined that the TSPA-SR report transparency is insufficient because of: process inadequacies, and ineffective and/or undocumented checking; lack of data traceability; and the lack of supporting objective evidence to sufficiently substantiate conclusions. This was identified as a potential significant condition adverse to quality at the closing meeting.

The observers agreed with the audit team's findings in this area.

4.5 Technical Summary

The technical observers were satisfied by the technical expertise and overall performance of the audit teams and technical staff participating in the audit. Audit team questions were appropriate and thorough, leading to identification of issues important for confirming the technical quality of the work reviewed. Staff were cooperative and candid in discussions with the audit teams. Technical observers were provided ample freedom to ask questions pertinent to the scope of the audit and were satisfied with the overall conduct of the audit sessions. Observers generally concur with the findings of the audit team. In particular, the lack of transparency in the documentation of the modeling work for the TSPA-SR appears to create a difficulty for independent technical reviewers in understanding the details of specific analyses (e.g., difficult to understand the details of how some of the more complicated barrier neutralization modeling efforts were done). The apparent misapplication of procedures or use of inadequate procedures for checking calculations has also led to identification of a situation where some TSPA calculations were not thoroughly checked by reviewers for technical adequacy and correctness. Most of the calculations associated with the TSPA-SR technical report were checked internally, according to the performance assessment staff. However little or no documentation was created as a direct result of time constraints. Most auditees expressed dissatisfaction with the amount of time allotted in the document development process to ensure sufficient quality. The following are summaries for segments of the audit that were observed.

4.5.1 Development of Potential Exposure Scenarios

The audit of development of potential exposure scenarios included a review of technical product input. The primary topics addressed by the audit team were: (i) the method of scenario development from the features, events, and processes database; (ii) scenario construction comprehensiveness; (iii) procedures governing the scenario development process; (iv) transparency of the scenario development process; (v) risk dilution introduced by the scenario development process; (vi) lack of clarity of identification of the system boundaries; and (vii) use of expert elicitation.

The audit team interviewed two technical staff members familiar with the scenario development process. The audit team concluded that no formal procedure exists for conducting scenario development, but the description of the process in reviewed documents was sufficiently explained and conforms to international standards. The observers concurred with the audit team finding that no issues were discovered for this part of the audit.

4.5.2 Planning and Quality Determinations

The audit of planning and quality determinations led to investigations related to transparency, traceability, and the inability to reproduce model results. The primary concerns addressed by the audit team were related to transparency and traceability and the review process used for the TSPA-SR.

The audit team explored the documentation of sensitivity analyses reported in Appendix G of the TSPA-SR. The process was determined to be transparent in the sense that the data and model files that were used can be easily located. However, information on how a file was modified for a particular task (i.e., degraded barrier analysis, sensitivity analysis) was not formally documented, and could only be determined through a laborious comparison of archived input files, leading to lack of transparency. This lack of transparency in TSPA modeling documentation can adversely impact reviews of the technical adequacy of the TSPA modeling work.

Questions were also raised on the decision both to: (i) deviate from the work plan by using AP3.11Q instead of AP3.12Q, for documentation and review of calculations; and (ii) not follow the intent of AP3.11Q, by providing insufficient documentation of the calculation review process. Technical staff members were asked to describe the document review process. The author of AP3.11Q stated that the intent of the procedure was to require the same level of review required by AP3.12Q. However, this point was not clear from the auditor's review of the AP3.11Q procedures (AP3.11Q contained fewer calculation check requirements overall and no review of technical adequacy). The observers concurred with the audit team conclusion that implementation of AP3.11Q by DOE was not documented to the same level of rigor as required by AP3.12Q, and that the methods and results reported in Appendix G of the TSPA-SR were not transparent and traceable. Without such documentation, there was no objective evidence that the technical adequacy of the calculations had been checked.

4.5.3 Review of Technical Product

The review of the technical product investigated the technical quality of the TSPA-SR. This part of the audit intended to look at the technical work conducted for the sensitivity analyses reported in Appendix G of the TSPA-SR. The audit team encountered immediate difficulty because of the inaccessible records and questionable review documentation discussed in the previous section.

The audit team also explored a concern raised by the observers about the lack of requirements for technical specialists to respond to warnings and error messages recorded in the run log produced during operation of the GoldSim model. The issue originated from observing discussions among auditors and technical specialists where it was found that TSPA-SR GoldSim error logs for stochastic calculations were not saved during code execution and therefore were not reviewed by the staff. This circumstance caused observers to question how staff was able to confirm that no significant run errors occurred during the TSPA-SR stochastic GoldSim runs. A related question was raised by observers regarding why the existence of

errors in the log files did not lead to generation of a software deficiency notice. Technical staff responded to the observer concerns. The technical staff members and the audit team agreed that no requirement exists for operators of the GoldSim model to review, respond to, and document run log messages. Although the technical staff members stated that a review of the run log error and warning messages had been conducted for the median-value problem (and no significant problems were identified), the observers concurred with the audit team recommendation that this process should be formally documented. Technical specialists stated that modifications to GoldSim since completion of the TSPA-SR work has provided the capability to output error logs for stochastic runs. Therefore, staff will have the capability to check this information in the future.

4.5.4 Software

The audit team reviewed the use of software for development of the TSPA-SR. The audit team discovered a problem with the use of ASHPLUME v2.0, which continues to be unqualified software. The process for qualifying ASHPLUME v2.0 for interim use was initiated, but not completed. The technical expert stated that results from ASHPLUME v2.0 were used as corroborative evidence and the software would not need to be qualified. Further, the expert stated that no data were generated, or included in the TSPA-SR, that originated from use of ASHPLUME v2.0, and that no decisions were based on results of ASHPLUME v2.0. This statement was the subject of debate and interpretation between the audit team and technical staff members. The observers concurred with the audit team finding that the unqualified status of ASHPLUME v2.0 was not properly documented in the TSPA-SR and, under the existing documentation in TSPA-SR, the software should have been qualified before use. Technical observers viewed the findings as primarily a procedural issue; however, the development status of software used in technical reports can impact the assessment of technical adequacy of calculations and confidence in results.

4.5.5 Records

The audit team reviewed the record package associated with the TSPA-SR ICN00 and TSPA-SR ICN01, to ensure that the appropriate QA procedures, specifically AP2.14Q, AP3.10Q, and AP3.11Q, had been followed. The review of the record package for the TSPA-SR ICN01 indicated that procedures had been followed. The audit team reported that the record package for TSPA-SR ICN00 was disorganized and made any assessment of technical adequacy exceedingly difficult. The audit team reported that it was not satisfied with the way the “story board” method was used to track the review process. At the post-audit meeting, the audit team indicated that no major problems had been discovered, but that this item would remain open and the investigation of the TSPA-SR ICN00 record package would continue into the following week.

5.0 NRC Staff Findings

During the audit exit, the observers expressed appreciation for the cooperation and responsiveness provided to them during their observation activities. In addition, the observers stated that they agreed with the audit team findings and recommendations, as presented at the audit exit. Also, during the audit exit, the observers stated that they will continue to interface with DOE and BSC and follow the progress that DOE and BSC are making to address the issues identified during this audit.

The NRC feels it is important to identify that the Phase 2 audit (August 20-24, 2001) discussed in this report did not fully address all of the areas identified in the scope of the Phase 1 Audit Report (M&O-ARP-00-13), dated October 23, 2000. Final planning for the Phase 2 audit identified a more limited scope than initially planned. The NRC believes the audit team did fully cover the more limited scope.

The scope of the Phase 1 Audit Report states: *"Note that two activities planned for the audit during phase 1 could not be assessed, i.e., development/analysis of scenarios and performance/documentation of the TSPA-SR model."* It further states: *"The Phase 2 audit, which is tentatively scheduled for the first quarter of fiscal year 2001, is to address the incorporation of design changes, performance of calculations, sensitivity analysis, evaluation of parameter ranges and uncertainties, transparency, and defensibility of TSPA-SR results and conclusions."* While the Phase 2 audit did cover many of these items, it only partially covered the performance of the TSPA-SR model and performance of calculations. The NRC's observation is that the Phase 2 audit did not cover evaluation of parameter ranges and uncertainties, the TSPA-SR model report documentation and review, or the defensibility of the TSPA-SR results and conclusions.

5.1 NRC Audit Observer Inquiries

The observers did not generate any Audit Observer Inquiries (AOIs) during the audit.

5.2 Closure of Previous NRC Audit Observation Inquiries

The following AOI has been closed:

AOI No. M&O-APR-01-01-01, February 2001, was written to identify an observer inquiry for ANL-EBS-MD-000033. Several agreements made at the NRC/DOE Technical Exchange (January 9-12, 2001, Pleasanton, CA) on Evolution of the near Field Environment (EMFE) indicate that new data and analysis will be presented in the "EBS: Physical and Chemical Environment Model AMR (ANL-EBS-MD-000033)," expected to be available in FY 02. The following NRC/DOE agreements point specifically to the FY 02 revision of this AMR: ENFE 2.04; ENFE 2.06; ENFE 2.08; ENFE 2.11; ENFE 2.13, and ENFE 2.18. ENFE 2.05 and ENFE 2.17 also point to this AMR, although they state the information can be provided in other documents as appropriate. During the M&O-ARP-01 audit of ANL-EBS-MD-000033, Rev. 01, in Las Vegas, NV (February 20-23, 2001), however, audit team members questioned the usefulness of producing additional revisions of this AMR. If data and analyses required to fulfill NRC/DOE agreements listed above are not presented in a FY 02 revision of the ANL-EBS-MD-000033 AMR, where will this information be presented?" (Refer to U.S. NRC's Observation Audit Report No. QAR-01-03).

This AOI has been closed based on DOE's response to the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance NRC Audit Observer Inquiry (AOI) from Audit M&O-ARP-01-01-01 provided in a letter from S. Brocoun to C.W. Reamer dated 10-01-01. The NRC reviewed the letter, and determined that the DOE response to this AOI was satisfactory. The NRC considers the status of the AOI from Audit M&O-ARP-01-01-01 to be closed.

5.2 Open NRC AOIs from Previous NRC Observations

The following AOI from a previous DOE audit observed by NRC, remains open:

AOI No. M&O-APR-01-02-4, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "The work upon which this model is based (Flint, et al., 1996, "Conceptual and Numerical Model of Infiltration at Yucca Mountain") is unqualified. (See OCRWM QA Audit Report M&O APR-00-04)(p. 9). Was information used to support conclusions made in the Infiltration AMR? If yes, describe how the Flint, et al. (1996) data were qualified and assumptions verified. NRC requests additional information and details. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."